

It is an object of the present invention to address the foregoing problems or at least to provide the public with a useful choice.

Further aspects and advantages of the present invention will become apparent from the ensuing description which is given by way of example only.

## 5 DISCLOSURE OF INVENTION

According to one aspect of the present invention there is provided a process for administering to an animal progressively increasing doses of one or more biologically active agents which are released over a predetermined period of time from a delivery means which is administered to an animal on a single occasion.

- 10 Preferably said one or more biologically active agents are selected from the list of antibiotics, anthelmintics, peptides, proteins, carbohydrates, DNA, RNA, hormones, neutraceuticals, vitamins, trace-elements, immunising agents or any combination thereof.

- 15 The biologically active agents may optionally comprise an adjuvant and/or a pharmaceutically acceptable carrier.

- 20 Preferably the progressively increasing doses comprise sequentially doubling doses of biologically active agent, or sequentially increasing doses such as 25, 50, 75, 100 or 4, 8, 32, 150 active units. The doses are chosen so as to elicit a desired response and are administered over a predetermined period of time from hours, days, weeks, and months or any combination thereof.

Preferably said one or more biologically active agents is an immunising agent and wherein said process comprises the administration to said animal of progressively increasing doses of one or more immunising agents which are released over a predetermined period of time from a delivery means which is administered to an

an episode of infection and the natural antibody response thereto.

The doses of the progressively increasing doses of antigen are chosen so as to elicit a favourable antibody response which includes the production of both high-affinity antibodies and antigen-specific memory lymphocytes.

- 5 Preferably, the progressively increasing doses of antigen are in the range of from 0.1  $\mu$ g to 1000  $\mu$ g.

Preferably, the predetermined period of time at which the one or more drugs are administered is selected from hours, days, weeks or months or any combination thereof.

- 10 The delivery means preferably comprises an immunising agent delivery composition which comprises means to enable progressively increasing doses of one or more immunising agents to be released over a predetermined period of time therefrom, when said delivery means is administered to an animal on a single occasion.

- 15 The present invention further provides an unloaded delivery means comprising an unloaded immunising agent delivery composition which comprises means to enable progressively increasing doses of one or more immunising agents to be released over a predetermined period of time once said immunising agent is loaded into said immunising agent delivery composition and when said delivery means is administered to an animal on a single occasion.

- 20 Preferably, the delivery composition comprises means to enable the delivery of one dose of said one or more antigens within hours/days/weeks/months of its administration and means to enable the delivery of further progressively increasing doses of the same or different antigens hours/days/weeks or months later.

The progressively increasing doses of said one or more immunising agents are

**WHAT WE CLAIM IS:**

1. A process for administering to an animal progressively increasing doses of one or more biologically active agents which are released over a predetermined period of time from a delivery means which is administered to an animal on a single occasion.
2. A process as claimed in claim 1 wherein said one or more biologically active agents are selected from the list of antibiotics, anthelmintics, peptides, proteins, carbohydrates, DNA, RNA, hormones, nutraceuticals, vitamins, trace-elements, immunising agents or any combination thereof.
3. A process as claimed in either claim 1 of claim 2 wherein said one or more biologically active agents comprise an adjuvant and/or a pharmaceutically acceptable carrier.
4. A process as claimed in any one of claims 1 to 3 wherein the progressively increasing doses comprise sequentially doubling doses of biologically active agents, or sequentially increasing doses such as 25, 50, 75, 100 or 4, 8, 32, 150 active units.
5. A process as claimed in any one of claims 1 to 4 wherein the predetermined period of time at which said one or more of biologically active agents are administered is selected from hours, days, weeks or months or any combination thereof.
6. A process as claimed in any one of claims 1 to 5 wherein said one or more biologically active agents is an immunising agent and wherein said process comprises the administration to said animal of progressively increasing doses of one or more immunising agents which are released over a predetermined period

of time from a delivery means which is administered to an animal on a single occasion.

7. A process as claimed in claim 6 wherein said one or more immunising agents comprise an antigen or combination of antigens.
8. A process as claimed in claim 6 or claim 7 wherein said one or more immunising agents comprise a vaccine or combination of vaccines.
9. A process as claimed in any one of claims 6 to 8 wherein said one or more immunising agents are selected from molecules that will induce protective immunity against a disease causing organism, or functional immunity or any combination thereof.
10. A process as claimed in any one of claims 6 to 9 wherein the progressively increasing doses of said one or more immunising agents are in the range of from 0.1  $\mu\text{g}$  to 1000  $\mu\text{g}$ .
11. A process as claimed in any one of claims 6 to 10 wherein the delivery means comprises an immunising agent delivery composition which comprises means to enable progressively increasing doses of one or more immunising agents to be released over a predetermined period of time therefrom, when said delivery means is administered to an animal on a single occasion.
12. A biologically active agent delivery composition comprising one or more biologically active agents whereby said composition comprises means to enable progressively increasing doses of said one or more biologically active agents to be released over a predetermined period of time from a delivery means which is administered to an animal on a single occasion.
13. A biologically active agent delivery composition as claimed in claim 12

wherein said one or more biologically active agents are selected from the list of antibiotics, anthelmintics, peptides, proteins, carbohydrates, DNA, RNA, hormones, neutraceuticals, vitamins, trace-elements, immunising agents or any combination thereof.

14. A biologically active agent delivery composition as claimed in either claim 12 of claim 13 wherein said one or more biologically active agents comprise an adjuvant and/or a pharmaceutically acceptable carrier.
15. A biologically active agent delivery composition as claimed in any one of claims 12 to 14 wherein the progressively increasing doses comprise sequentially doubling doses of biologically active agents, or sequentially increasing doses such as 25, 50, 75, 100 or 4, 8, 32, 150 active units.
16. A biologically active agent delivery composition as claimed in any one of claims 12 to 15 wherein the predetermined period of time at which said one or more of biologically active agents are administered is selected from hours, days, weeks or months or any combination thereof.
17. A biologically active agent delivery composition as claimed in any one of claims 12 to 16 wherein said one or more biologically active agents is an immunising agent and wherein said delivery composition comprises means to enable progressively increasing doses of one or more immunising agents to be released over a predetermined period of time from a delivery means which is administered to an animal on a single occasion.
18. A biologically active agent delivery composition as claimed in claim 17 wherein said one or more immunising agents comprise an antigen or combination of antigens.
19. A biologically active agent delivery composition as claimed in claim 17 or

claim 18 wherein said one or more immunising agents comprise a vaccine or combination of vaccines.

20. A biologically active agent delivery composition as claimed in any one of claims 17 to 19 wherein said one or more immunising agents are selected from molecules that will induce protective immunity against a disease causing organism, or functional immunity or any combination thereof.
21. A biologically active agent delivery composition as claimed in any one of claims 17 to 20 wherein the progressively increasing doses of said one or more immunising agents are in the range of from 0.1  $\mu\text{g}$  to 1000  $\mu\text{g}$ .
22. A biologically active agent delivery composition as claimed in any one of claims 12 to 21 wherein the delivery composition comprises two or more types of microspheres or microparticles, each type of microsphere or microparticle containing a different dose of one or more biologically active agents and comprising biodegradable material which will degrade over a known time period so that the lowest dose of biologically active agents is released from a first type of microsphere or microparticle at a set time after administration, followed by the next highest dose of biologically active agents at the next predetermined time etc.
23. A biologically active agent delivery composition as claimed in any one of claims 12 to 22 wherein the delivery composition is located within a delivery means comprising a bioerodable device that releases progressively increasing amounts of the biologically active agents as it erodes.
24. A biologically active agent delivery composition as claimed in any one of claims 12 to 23 wherein the delivery composition is administered to an animal by way of injection, ingestion or implantation.

25. A biologically active agent delivery composition as claimed in claim 24 wherein the administration of the delivery composition takes place shortly after birth of an animal, or when maternally-derived antibody has decreased sufficiently for the young animal to be able to respond to the vaccination, and provides immunity without the need for further booster administration.
26. An unloaded delivery means for use in a process as described in any one of claims 1 to 11 comprising an unloaded biologically active agent delivery composition which comprises means to enable progressively increasing doses of one or more biologically active agents to be released over a predetermined period of time once said biologically active agent is loaded into said biologically active agent delivery composition and when said delivery means is administered to an animal on a single occasion.
27. A delivery means for use in a process as described in any one of claims 1 to 11 wherein the delivery composition is located within comprising a multi-compartmental capsule containing progressively increasing doses of one or more biologically active agents within the compartments, said delivery means comprising an outer wall made of a biodegradable substance which degrades over a pre-set period of time to release the smallest dose of biologically active agents, and one or more inner compartmental walls made of the same or different material that degrade over a longer period of time to release progressively increasing pulses of the biologically active agents
28. A delivery means as claimed in claim 27 wherein the biodegradable material of the outer wall is be selected from the group comprising cholesterol/lecithin, polylactide and/or polyglycolide copolymers, one or more of a number of cellulose polymers, polyacrylic acid, polymethylmethacrylate, cross-linked polyacrylic acid, polycaprolactone, polyvinylpyrrolidine, polyvinylalcohol,

polyethylene glycol, agarose, DEAE dextran microspheres, starch microspheres and/or albumin microspheres or gelatine microspheres or any combination thereof.

29. A delivery means as claimed in claim 27 or claim 28 wherein the pre-set period of time within which the outer wall and inner compartmental walls degrade may be selected from hours, days, weeks or months.
30. A delivery means as claimed in any one of claims 26 to 29 wherein the delivery means is selected from the group comprising, multi-compartmental capsules and capsules having an osmotic pump therein.
31. A process substantially as described herein with reference to and as illustrated by the accompanying description and drawings.
32. A biologically active agent delivery composition substantially as described herein with reference to and as illustrated by the accompanying description and drawings.